

VZCZCXRO2918
RR RUEH DU RUEHJO
DE RUEHSA #0004/01 0020803
ZNR UUUUU ZZH
R 020803Z JAN 08
FM AMEMBASSY PRETORIA
TO RUEHC/SECSTATE WASHDC 3069
RUEHRC/USDA FAS WASHDC 1976
INFO RUEHTN/AMCONSUL CAPE TOWN 5188
RUEHJO/AMCONSUL JOHANNESBURG 7806
RUEH DU/AMCONSUL DURBAN 9469

UNCLAS SECTION 01 OF 04 PRETORIA 000004

SIPDIS

SIPDIS

SENSITIVE BUT UNCLASSIFIED

DEPT FOR EB/TPP/ABT, OES/PCI, AND AF/S
DEPT PASS EB/TPP/ABT - JMENARD, TLERSTEN, AND MKOCH
USDA FAS FOR OSTA/NTPMB/MICHAEL HENNEY AND ANTHONY GILBERT
USDA APHIS FOR THOMAS C. NESBITT

E.O. 12958: N/A

TAGS: [EAGR](#) [ECON](#) [ETRD](#) [SENV](#) [SF](#)

SUBJECT: BIOTECH OUTREACH ACTIVITY REPORT

REF: A) STATE 202514 B) PRET 000357

¶1. (U) Summary: From September 15-28, 2007, FAS/Pretoria hosted Thomas C. Nesbitt, Outreach and Communications Specialist/Biotechnology Regulatory Service(BRS)/ Animal Plant Health Inspection Service(APHIS)/USDA to undertake biotechnology outreach activities funded by the Department of State's Bureau for Economic, Energy, and Business (EEB). Dr. Nesbitt participated in several meetings related to agricultural biotechnology regulatory policy with government officials, researchers, and industry representatives in Pretoria, South Africa. He gave presentations and discussed U.S. regulatory policy with staff at the Council for Scientific and Industrial Research, the Department of Environment and Tourism, the GMO Act Executive Council, the Department of Trade and Industry, and the Department of Agriculture. He also gave a lecture hosted by the Public Understanding of Biotechnology Project (PUB) and presentations at two events organized by AfricaBio. End Summary.

¶2. (U) Funding for this activity was provided by EEB's biotech outreach funds to improve the understanding of the U.S. regulatory system and risk assessment methodologies. Representatives from the Department of Environment and Tourism had requested to discuss risk assessment methodologies with APHIS regulators - a significant invitation from South African officials who have been reticent to engage with U.S. officials, and whose role in the South African regulatory system has been recently elevated.

Background

¶3. (U) Commercial production of genetically engineered (GE) crop varieties has been authorized in South Africa since 1997. In 2006, acreages of GE varieties accounted for approximately 44% of corn, 79% of soybean, and 92% of cotton. The approval process for both field releases and commercial commodity imports, first defined in the 1997 Genetically Modified Organism (GMO) Act is as follows: An application is first submitted to the GMO Registrar in the National Department of Agriculture. The Registrar reviews the application for compliance with the Act, and then submits the package to an independent scientific advisory committee for scientific review and risk assessment. This committee makes recommendations to the Registrar to either approve or to seek additional information. Once the committee makes a recommendation, the Registrar forwards the recommendation to an Executive Council that administers the GMO Act and makes the final decision regarding the approval. The Executive Council is composed of representatives from eight national-level government ministries: Department of Agriculture (DoA), Department of Science and Technology (DST), Department of Environment and

Tourism (DEAT), Department of Trade and Industry (DTI), Department of Health (DoH), Department of Labor (DoL), Department of Water Affairs and Forestry (DWAF), and Department of Arts and Culture (DAC)

¶4. (SBU) Several factors are reported to have contributed to a slowdown in field release and commercialization approvals in recent years, including: significant personnel change in some agencies with accompanying loss of institutional memory; amendment of the National Environmental Management and Biodiversity Act in 2004, giving new responsibilities to DEAT; addition of DWAF and DAC to the Executive Qresponsibilities to DEAT; addition of DWAF and DAC to the Executive Council following revisions of the GMO Act in 2007; and an economic impact analysis on commodity clearance being conducted by DTI.

Council for Scientific and Industrial Research (Sept. 17)

¶5. (U) In a two-hour meeting, Dr. Nesbitt gave presentations on the U.S. Coordinated Framework, an overview of other Federal acts affecting biotech (e.g., NEPA, TES), and an in-depth review of notification, permit, and petition procedures. CSIR is an R&D organization funded through the Department of Science and Technology. Meeting participants included research scientists and breeders developing transgenic sorghum varieties (for which release permits had recently been denied by the Executive Council), researchers developing vaccine-producing crops, and ecologists conducting biotechnology-related risk research. Several staff from DEAT were also present.

¶6. (SBU) Much of the discussion following the presentations centered on criticism of South Africa's ability to effectively use the expert input of its biotech scientific advisory committee. Several meeting participants had the perception that the Executive

PRETORIA 00000004 002 OF 004

Council disregarded the advice of the advisory committee, and would second-guess assessments by requesting additional "safety" information from applicants with perhaps dubious scientific justification.

Department of Environment and Tourism (Sept. 17)

¶7. (U) The afternoon included an informal, two-hour discussion with DEAT's Director of Biosafety/GMOs and the Director of Biodiversity Management. Discussion centered on the two different authorities used by DEAT to regulate biotech crops: the 1998 National Environmental Management Act (NEMA) and the more recently-amended 2004 National Environmental Management Biodiversity Act (NEMBA). The latter explicitly gives DEAT the authority to conduct an "environmental impact assessment" if the DEAT Minister has reason to believe a biotech crop could impact biodiversity and to conduct "monitoring"; the former is a broader environmental protection authority. DEAT is attempting to develop internal procedures to reconcile how and when it will conduct its risk assessments under the two different authorities, and how this may or may not be reconciled with the risk evaluations conducted under the GMO Act by the Executive Council, of which DEAT is a member. Participants also discussed the similar challenges faced by APHIS regulators in conducting risk assessments under the authorities of both NEPA and the Plant Protection Act. Ironically, APHIS is now moving towards separating the two assessments; DEAT was considering combining theirs. It should be noted that none of the various assessments to be conducted by DEAT would be publicly available (Note: Dr. Nesbitt enquired about this directly). Rather, they seemed to be intended as internal advisories for the GMO Act Executive Council.

GMO Act Executive Council (Sept. 18)

¶8. (U) Dr. Nesbitt presented on overview of U.S. regulatory policy and APHIS' process to this meeting of the Executive Council. Participants asked many questions about specific policy issues, including stacked genes, LLP/AP, regulation of pharma trials, inspection and monitoring, recent rice issues and lawsuits, etc. He

also spent a great deal of time discussing the Coordinated Framework; in particular, how the three agencies are able to make decisions independently and the consequences of working with three different agencies (differences in timing, different implications for commercialization, different legal weights of reviews (i.e. FDA), etc).

Department of Trade and Industry (Sept. 19)

¶9. (SBU) Discussion that followed a presentation on the U.S. regulatory policy ranged very widely, including: liability and redress, identity preservation and labeling, commodity clearance, food safety, etc. Some participants seemed to be very positive about biotechnology, but, for example, felt that "labeling is a very good thing." Others seemed very concerned about "unresolved" food safety issues, and asked many questions about recent quasi-scientific publications (Pusztai, etc.). In general, DTI staff expressed a desire to study the economic impacts of biotech commodity imports, but appeared to be grappling with what to analyze and how.

Department of Agriculture (Sept. 20)

Q-----

¶10. (U) Dr. Nesbitt gave a short talk on U.S. and APHIS regulation of biotechnology to a small group of NDA officials who were primarily plant protection specialists from the Agricultural Products Inspection Service and the Pest Risk Assessment group within the Plant Health program. There was some discussion of biotechnology import permits and inspections (especially BRS' collaboration with Plant Protection and Quarantine (PPQ)), but participants did not play an active role in regulating biotechnology in South Africa.

Public Understanding of Biotechnology (Sept. 20)

¶11. (U) In this meeting, Dr. Nesbitt gave a public talk on risk perception, risk communication, and public perception of biotechnology. The talk was hosted by the Public Understanding of Biotechnology (PUB) Project, an outreach program funded by the South African Agency for Science and Technology Advancement (SAASTA, a

PRETORIA 00000004 003 OF 004

business unit within the Department of Science and Technology). PUB has a nationwide outreach program with educational materials and brochures, grade school education programs, public meetings and lectures, etc., and its managers appeared to have well-established relationships with biotechnology risk communication experts in the United States and internationally. Talk attendees included PUB staff, several interns and staff from DEAT and DST, and a few others.

AfricaBio Business Breakfast (Sept. 21)

¶12. (U) Dr. Nesbitt presented a talk to AfricaBio's business council on U.S. regulation of biotechnology, with some added emphasis on upcoming changes to 7CFR340. As the participants were largely from the local research and business community, conversation following the talk was similar to discussions with representatives of these groups earlier in the week.

AfricaBio Workshop (Sept. 26)

¶13. (U) AfricaBio organized a week-long workshop entitled "Biosafety Course of the Non-Biotechnologist" (Sept. 25-29). Participants included primarily policy makers, regulators, and risk assessors from several countries in south and east Africa. Dr. Nesbitt gave a very short overview of the U.S. regulatory system, but time for discussion was limited.

¶14. (U) Explaining the inner workings of the U.S. regulatory system to South African regulators and policy makers seemed to have a large impact on the South African's perception of U.S. policy. Misunderstanding of the U.S. regulatory system (or even of its existence at all) was widespread. Throughout the week, many government regulators who initially seemed skeptical of presentations expressed pleasant surprise to learn that the U.S. "actually thought about risk" and "didn't just say 'yes' to everything multinational companies asked for." Audiences were often surprised that U.S. regulators included risk assessors and scientists from a wide range of disciplines, and that the United States is assessing many of the same kinds of risks and regulatory challenges they were. These meetings have the potential to be the early foundations for relationships between U.S. and South African regulators as regulators, benefiting from exchange of technical expertise and discussion of the similar challenges each faces.

¶15. (SBU) A significant difference between the U.S. and South African regulatory systems lies in the role of the GMO Act Executive Council (EC) as the final decision-making body in South Africa. Unlike in the United States, where each of the three coordinated framework agencies makes its decision independently based upon distinct expertise and authorities, in South Africa the EC makes a single consensus decision. A scientific advisory council and each individual agency submit separate assessments to the EC, but these documents are not made public and are all apparently open for reconsideration at the EC level. When applications are made to the GMO Registrar, the Registrar formally solicits public comment, but individual EC members also independently receive public comment through back channels which they take into consideration. The EC also meets infrequently, often requesting new data of applicants. Qalso meets infrequently, often requesting new data of applicants through the Registrar, but not considering the new data until much later meeting cycles. Perhaps most significantly, the consensus nature of the EC decision-making means that individual members have the ability to request additional data from applicants outside their particular areas of expertise or regulatory jurisdiction (as a hypothetical example, an economist from the Department of Trade and Industry may wish to have additional food safety data). The ad hoc rethinking at the EC level does not appear to be couched within any formal risk assessment framework. Because only the final decision document is made public and all of the deliberations occur behind closed doors, applicants expressed frustration that the decision-making process is not very transparent and it is difficult to reconstruct on what basis individual decisions are made.

¶16. (SBU) The decision-making ability of the Executive Council might be improved by building the risk-assessment competence and confidence of each of the individual member agencies. In many instances, the persons who are responsible for their agency's separate risk assessments are also the same individuals who sit on the EC. Improving this confidence might make separate agency risk

PRETORIA 00000004 004 OF 004

assessments "pass through" the EC intact, and perhaps be better communicated in the final decision documents. Continuing to foster working relationships and technical exchanges between U.S. and South African regulators at the risk assessment level is likely to benefit both countries.

¶17. (U) Comment: Post looks forward to developing this relationship further in 2008 and will submit its proposal to EEB in January. End comment.
Bost